

REMARKS/ARGUMENTS

Reconsideration of the present application is respectfully requested. With this amendment, claims 1, 2, 12, 13, 14-16, 20, 21, and 27-29 are pending.

Claim Rejections - 35 USC §103

Claims 1, 2, 13, 14-16, 20, 21 and 27-29 are rejected under 35 USC §103(a) as being unpatentable over Saunders, et. al. (US Patent No. 6,977, 269) in view of Eenennaam, et. al. (US 2003/0154513).

The Office Action states: "Saunders, et. al. teach a method of improving the tissue quality of an animal (see col. 3, lines 18-21) - including the cattle of instant claim 13 ... by feeding the animal vitamin E (see col. 1, lines 41-43)."

The Office Action further states: "Eenennaam, et. al. teach transgenic plants modified to express polypeptides of tocopherol biosynthesis pathway (see abstract).... The Eenennaam, et. al. reference teaches an animal diet comprising mixed tocotrienols comprising oil from a plant that has been genetically modified to have elevated mixed tocotrienol levels, as recited in instant claims 16 and 29."

The Office Action asserts: "While Eenennaam, et. al. do not explicitly teach all the instant claimed concentration of tocotrienols, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable concentration through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.... Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.... Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant concentration."

The Office Action concludes: "It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use tocotrienols as a method of improving cattle meat quality, as taught by Saunders, et. al. in view of

Eenennaam, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to add tocotrienols to an animal feed for the beneficial effects of improved meat quality, as explained by Saunders, et. al. and Eenennaam, et. al."

The rejection is respectfully traversed.

As the instant specification, knowledge of one of skill in the art, and the cited reference make clear, the words "Vitamin E", "tocopherol", and "tocotrienol" are not analogous terms.

"Vitamin E" is an umbrella expression for "...a class of lipid-soluble anti-oxidants that includes α , β , γ , and δ -tocopherols and α , β , γ , and δ -tocotrienols.... Vitamin E is more appropriately defined chemically as alpha-tocopherol." (See Eenennaam et al, paragraph [0004]). Both the instant specification and the cited reference differentiate between the tocopherols and tocotrienols e.g.: "...vitamin E in the form of alpha-tocopherol acetate...." (See Saunders, et. al., col.1, lines 41-41, and the instant specification paragraph [0008]).

As argued in applicant's previously filed response, Saunders, et. al. teaches the danger in assuming the efficacy of any particular Vitamin E anti-oxidant compound without experimental validation.

Further, the state of the art at the time the present application was filed, distinguishes the tocopherols and tocotrienols as distinct compounds, structurally and functionally, resulting from different biochemical pathways. See Yap, et. al., 2003 (copy attached for the Examiner's convenience), page 53, first and second paragraphs of Introduction which states: "...The difference between the tocopherols and tocotrienols lies mainly in the former having a saturated phytyl chain, while that of the latter is unsaturated, with three double bonds at 3', 7', and 11' positions.... In recent years tocotrienols have generated much interest as they have been reported to possess certain biological activities that were not observed with the tocopherols...." See also US Pat. No. 7,154,029 which states: "Tocopherol side chains are derived

from phytyl-pyrophosphate (PP), and the tocotrienol side chains are believed to be derived from geranylgeranyl-PP (Soll, J., et al. (1980) *Arch. Biochem. Biophys.* 204:544-550)."

The disclosure of Saunders, et. al., as discussed previously, does not teach the use of tocotrienols in feed to improve meat quality.

Since Saunders, et. al. does not teach, suggest, or disclose, the use of tocotrienols in a livestock feed diet, the determination of effective concentrations of mixed tocotrienols in the diets disclosed in the instant invention present a distinct invention, rather than mere routine or manipulative experimentation to determine.

Eenennaam, et. al. does not present reasoning, citations, or evidence that the transgenic plants disclosed therein contain elevated levels of mixed tocotrienols.

Therefore, one of skill in the art could not use Saunders, et. al. or Eenennaam et. al., alone or combined, with any reasonable expectation of success to produce the present invention. Accordingly, claims 1, 2, 13, 14-16, 20, 21, and 27-29 are not obvious in view of the cited art.

The Office Action asserts in regard to Eenennaam, et. al.: "...each claim of an issued patent enjoys a presumption of validity.... Thus, examiner respectfully submits that it may be inferred that the transgenic plants of Eenennaam, et. al. have elevated levels of tocotrienols."

It is noted that Eenennaam, et. al. is not an issued patent but a patent publication so there is no presumption of the validity of the claims cited by the Examiner. Further, the claims cited by the Examiner in Eenennaam, et. al. recite only α -tocotrienol, not the mixed tocotrienols of the invention.

In view of the above remarks, it is submitted that the rejections under 35 USC §103(a) should be withdrawn.

Double Patenting

Claims 1, 2, 12, 13, 14-16, 20, 21, and 27-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting. The claims are rejected as unpatentable over claims 1-27 of co-pending US Patent Application 11/153,463 ('463).

The Office Action states: "Although the conflicting claims are not identical, they are not patentably distinct from each other because '463 claims a method of improving the tissue quality of an animal, including ruminant animals, using mixed tocotrienols. See claims 1, 12, and 19."

The rejection is respectfully traversed: the rejection is provisional as the cited reference is not yet patented. Therefore, no response is presently needed to this provisional rejection.

Claims 1, 2, 12, 13, 14-16, 20, 21, and 27-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting. The claims are provisionally rejected as unpatentable over claims 1-20 of co-pending Application No. 11/530,075 ('075).

The Office Action states: "Although the conflicting claims are not identical, they are not patentably distinct from each other because '075 claims a method of improving the tissue quality of an animal, including ruminant animals, using mixed tocotrienols. See claims 1, 10, and 13."

The rejection is respectfully traversed: the rejection is provisional as the cited reference is not yet patented. Therefore, no response is presently needed to this provisional rejection.

The Office Action asserts: "The transitional term 'comprising', which is synonymous with 'including', 'containing', or 'characterized by', is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.... Thus, examiner respectfully submits that the scope of the instant claims is

commensurate with the claims of co-pending Application Nos. 11/153,463 and 11/530,075.

The Examiner has not presented the reasoning whereby a person of skill in the art would conclude that the invention defined in the present claims would be an obvious variation of the claims in '075 or '463 in light of their respective specifications. The patentable distinctions between the cited applications and the present application have been discussed in the prior responses and, to expedite prosecution, will not be repeated here.

In view of the above remarks, it is submitted that the rejections under nonstatutory obviousness-type double patenting should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, it is submitted that the rejections of the claims under USC 103(a) and nonstatutory obviousness-type double patenting are overcome. It is respectfully submitted that this application is now in condition for allowance.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

Respectfully submitted,

/Kathryn K. Lappegard/
Kathryn K. Lappegard, Reg. #46,857

PIONEER HI-BRED INTERNATIONAL, INC.
Corporate Intellectual Property
7250 N.W. 62nd Avenue
P.O. Box 552
Johnston, Iowa 50131-0552
Phone: (515) 253-5707
Facsimile: (515) 334-6883